CHAPTER 11

Regulations

INTRODUCTION

Biosolids are the only beneficial waste that is regulated by the United States Environmental Protection Agency (USEPA). These regulations pertain to land application of biosolids, including compost and other forms of transformed biosolids materials. States must adhere to the USEPA regulations at a minimum. State agencies may impose more stringent regulations or guidelines. Several agencies in the United States, Canada and Europe have chosen to issue guidelines rather than regulations. Often documents issued as guidelines are used as regulations.

Regulations are important. They provide the public with confidence that the product has met certain criteria and should be safe to use.

The objective of this chapter is to provide current regulations, guidelines and standards prevailing in the United States, Canada and several countries in Europe. This chapter reviews the concepts and approaches leading to regulations and discusses the criteria that should be regulated.

CONCEPTS AND APPROACHES TO REGULATIONS

Kennedy (1992) presented three basic approaches to the development of regulations as related to product use:

- No net degradation
- Risk-based approach
- Best achievable approach

The "no net degradation" concept is based on the premise that the application of biosolids should not increase the level of a heavy metal or other contaminant in the soil. Several European countries and Canadian Provinces have set guidelines or regulations based on this concept. However, no net degradation begs the question: What should be used as a soil base level?

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Soil quality varies greatly within a small area; urban soils may have higher levels of lead from leaded gasoline than rural areas. Regional standards would have to be established based on fluctuations in soil quality. If no net degradation were used on a site-by-site basis, it would create excessive sampling requirements and would allow the use of lower quality material on areas that are already contaminated.

Another problem with the no-net-degradation concept: Soils are continuously amended with fertilizers, pesticides, herbicides and other chemicals. This not only changes the baseline quality of the soil, but also illustrates the illogic in singling out a single material as the only regulated material.

The "risk-based approach" considers the potential risk to humans, animals, plants and soil biota, as well as environmental consequences. This approach evaluates the potential toxic effects of a chemical on the individual (human, animal, or plant) or environmental entity. The risk-based approach considers the risk in relation to other risks in the environment. This approach is dependent on having sufficient good data. The most comprehensive risk evaluation focused on heavy metals, resulting in USEPA 40 CFR 503 regulations for the disposal and use of biosolids. This approach was not used for pathogens.

The "best achievable approach" ignores health and environmental aspects and primarily considers technology and economics. Standards are based on what technology can achieve.

United States

U.S. federal regulations dealing with land application of biosolids falls under the jurisdiction of the USEPA. Enforcement is through USEPA regions, with the aid of state regulatory agencies. Those states with delegation have regulatory responsibility.

Regulations promulgated by USEPA cover biosolids or any material containing biosolids. These regulations were required by the Clean Water Act Amendments of 1987 [Sections 405(d) and (e)] as amended (33 U.S.C.A. 1251, *et seq.*). The regulations were published in the *Federal Register* (58 FR 9248 to 9404) as The Standards for the Use or Disposal of Sewage Sludge, Title 40 of the Code of Federal Regulations, Part 503. The 503 rule was published on February 19, 1993 and became effective on March 22, 1993. It was amended on February 25, 1994 (59 FR 9095) for molybdenum. The pollutant concentration limits and annual pollutant loading rates for molybdenum were deleted. Only the ceiling concentration limit of 75 mg/kg was retained.

Two other pollutant limits (for Cr and Se) were contested in the courts. Lawsuits were filed by Leather Industries of America, Inc., Association of Metropolitan Sewerage Agencies, Milwaukee Metropolitan Sewerage District and the city of Pueblo, Colorado. On March 5, 1993, Leather Industries of America filed a petition with the U.S. Circuit Court of Appeals seeking review of the pollutant limits for Cr. Three months later, on June 17, 1993, the City of Pueblo, Colorado filed a petition

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for review with the U.S. Court of Appeals challenging the Se pollutant limits. On October 25, 1995, USEPA deleted the pollutant limits for Cr and modified the Se limit to 100 mg/kg.

These actions point out important and significant distinctions between regulations and guidelines. Regulations can be overhauled or modified if new data become available or if the regulations are not equally applied. In addition to heavy metals, the 503 rule regulates pathogens and vector attraction. On December 23, 1999 in the *Federal Register* Volume 64, Number 246, pages 72045–72062, USEPA published a proposal to amend the management standards for sewage sludge. A numeric concentration limit is proposed for dioxin and dioxin-like compounds in sewage sludge that is applied to the land, as well as monitoring, record keeping and reporting requirements for dioxins in land-applied sewage sludge.

Much of the discussion in this chapter is from four USEPA documents.

1. *Federal Register.* Friday February 19, 1993. *Standards for the Use or Disposal of Sewage sludge; Final Rules. Part II* Environmental Protection Agency. 40 CFR Part 257.
2. USEPA. Office of Wastewater Management (4204). A Plain English Guide to the EPA Part 503 Biosolids Rule. EPA/832/R-93/003. September 1994.
3. USEPA. Office of Wastewater Management (4204). Guide to the Biosolids Risk Assessments for the Part 503 Rule. EPA832-B-95-005. Unpublished document. Courtesy of Dr. J. Walker.
4. USEPA. Office of Research and Development. Environmental Regulations and Technology. Control of Pathogens and Vector Attraction in Sewage Sludge. EPA/625/R-92/013. Revised October 1999. Washington, D.C.

The 503 rule was designed to protect public health and the environment from "any reasonably anticipated adverse effects of certain pollutants and contaminants that may be present in [biosolids]" (USEPA, 1994). USEPA clearly stated that it promotes the beneficial use of biosolids. A very intensive risk assessment was conducted. The rule-making took 9 years and evaluated research from the previous 25 years. In 1984 USEPA considered 200 pollutants identified in the "40 Cities Study." The selection of the 200 pollutants was based on the following criteria:

- Human exposure and health effects
- Plant uptake of pollutants
- Phytotoxicity
- Effects in domestic animals and wildlife
- Effects in aquatic organisms
- Frequency of pollutant occurrence in biosolids

This list of pollutants was submitted for review by four panels. The panels recommended that approximately 50 of the 200 pollutants listed be further studied. In the final regulations, USEPA addressed 24 pollutants using 14 exposure pathways (Ryan and Chaney, 1995). The 24 pollutants were:

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Organics	Heavy Metals
Aldrin/dieldrin (total)	Arsenic
Benzene	Cadmium
Benzo(a)pyrene	Chromium
Bis(2-ethylhexyl)phthalate	Copper
Chlordane	Lead
DDT/DDE/DDD (total)	Mercury
Heptachlor	Molybdenum
Hexachlorobenzene	Nickel
Hexachlorobutadiene	Selenium
Lindane	Zinc
N-Nitrosdimethylamine	
Polychlorinated biphenyls	
Toxaphene	
Trichloroethylene	

Risk assessment followed four basic steps (USEPA, 1995).

- Hazard identification: Can the identified pollutants harm human health or the environment?
- Exposure assessment: Who is exposed, how do they become exposed and how much exposure occurs? Highly exposed individuals were identified and their exposure to pollutants in biosolids evaluated. Fourteen exposure pathways were identified for land
  application of biosolids (see Table 11.1).
- Dose–response evaluation. What is the likelihood of an individual developing a particular disease as the dose and exposure increases? These two EPA toxicity factors were used whenever available:
  — Risk reference doses (RFDs) — daily intake
  — Cancer potency values (q_1*s) — conservative indication of the likelihood of a chemical inducing or causing cancer during the lifetime of a continuously exposed individual.
- Risk characterization: What is the likelihood of an adverse effect in the population exposed to a pollutant under the conditions studied? Risk is calculated as: Risk = Hazard ¥ Exposure. Hazard refers to the toxicity of a substance determined during the hazard's identification and dose–response evaluation and exposure is determine through the exposure assessment (USEPA, 1995). EPA made a policy decision to regulate risk at 1×10^{-4}.

The general approach USEPA utilized in developing pollutant soil loading limits follows (Ryan and Chaney, 1995):

- Delineation of pollutants of concern in biosolids.
- Identification of potential pathways for exposure and receptors (humans, soil biota, plants and animals) to several pollutants through land application of biosolids.
- Identification of dose–response relationships for the receptors and pollutants of concern.

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- Determination of maximum acceptable loading rates of biosolids to land for each pollutant based on the most limiting value for all evaluated pathways.
- Determination of the pollutant limits (cumulative soil pollutant application limit and maximum allowed biosolids pollutant concentration). This was obtained from maximum loading rates and biosolids concentration from the National Sewage Sludge Survey.

Several key assumptions were used in determining the pollutant limits:

- The target organism was the highly exposed individual (HEI) rather than the most exposed individual (MEI). The HEI was a realistic individual, whereas the MEI was unrealistic and did not exist.
- EPA used the lifetime exposure criteria of 70 years. For home gardeners producing their own food, it was assumed that 59% of the food would be grown in home gardens amended with biosolids.
- Uptake slopes for pollutants by crops were assumed to be linear even though the data indicated a curvilinear slope. This was believed to be more conservative.
- Cancer risk for all biosolids use was set at 1×10^{-4}.
- Data for plant uptake were based on field data when available.
- Human dietary exposure to pollutants in biosolids was revised from the early assessment by apportioning food consumption among several different age periods during the lifetime of the 70 years of the HEI.
- The final rule evaluated all organic pollutants proposed for the 503 rule. The levels found by the National Sewage Sludge Survey showed that organic pollutants were at low levels and in the evaluation did not pose significant risks to public health or the environment. USEPA is currently considering a zero limit for PCBs.

Examples of the risk assessment and the determination of the pollutant limits are shown for arsenic. The first analysis is for Pathway 1, where, over a lifetime, an adult consumes crops grown on biosolids-amended soil. The second example uses Pathway 3, a child ingesting biosolids. Based on these analyses it was determined that Pathway 3 was the limiting pathway. These analyses are based on USEPA (1995):

$$RIA = \frac{RfD * BW}{RE} TBI * 10^3 \tag{11.1}$$

where

RIA = allowable dose of pollutant without adverse effects
RfD = reference dose in mg/kg-day; for As = 0.0008 mg/kg-day
BW = human body weight, 70 kg
RE = relative effectiveness of ingestion exposure, 1.0, no units
TBI = total pollutant intake from all background sources in water, food and air, 0.012 mg/day

For arsenic in biosolids as applied to pathway 1:

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Table 11.1 U.S.EPA Risk Assessment Pathways for Application of Biosolids to Soil

Pathway	Highly Exposed Individual (HEI) or Receptor
1. Sludge–soil–plant–human	Protection of consumers who eat produce grown in soil using sewage sludge. 2.5% of intake of grains, vegetables, potatoes, legumes and garden fruit is assumed to be grown on sludge-enriched soil.
2. Sludge–soil–plant–home gardener	Home gardener who produces and consumes potatoes, leafy vegetables, legume vegetables, root vegetables and garden fruit. 60% of HEI's diet is assumed to be grown on sludge-amended soil.
3. Sludge–soil–child	Assessment of the hazard to a child ingesting undiluted sewage sludge. Sewage sludge ingestion was 0.2 g dry weight/day/5 years.
4. Sludge–soil–plant–animal–human	Human exposure from consumption of animal products. 40% of the HEI's diet of meat, dairy products, or eggs is assumed to come from animals consuming feed from soil to which sludge was applied. In a nonagricultural setting, a human consumes products from wild animals that ate plants grown on sludge-amended soil. The HEI is also assumed to be exposed to a background intake of a pollutant.
5. Sludge–soil–animal–human	The direct injection of sewage sludge by animals and the consumption by humans of the contaminated tissue. Direct ingestion of sludge by animals, where it has been surface applied. When sewage sludge is injected into the soil or mixed into the plow layer, grazing animals ingest the soil containing sludge. The HEI is also assumed to be exposed to a background intake of a pollutant.
6. Sludge–soil–plant–animal toxicity	Protection of the highly sensitive/exposed herbivorous livestock that consume plants grown on sewage sludge-amended soil. It is assumed that the livestock diet consists of 100% forage grown on sewage sludge-amended land and that the animal is exposed to a background pollutant intake.
7. Sludge–soil–animal toxicity	Protection of the highly sensitive/highly exposed herbivorous livestock which incidentally consume sewage sludge adhering to forage crops and/or sewage sludge on the soil surface. The amount of sewage sludge in the livestock diet is assumed to be 1.5% and the animal is exposed to a background pollutant intake.
8. Sludge–soil–plant toxicity	Evaluation of risk to plant growth (phytotoxicity) from pollutants in sludge. Probability of 50% reduction of plant growth associated with a low probability of 1×10^{-4}.
9. Sludge–soil–soil–biota toxicity	Protection of highly exposed/highly sensitive soil biota. Criteria for this pathway have been set using earthworm (*Eisenia foetida*) data.
10. Sludge–soil–soil biota–predator of soil biota toxicity	Protection of the highly sensitive/highly exposed soil biota predator. Sensitive wildlife that consume soil biota that has been feeding on sewage sludge-amended soil. Chronic exposure assumes that 33% of the sensitive species' diet is soil biota.
11. Sludge–soil–airborne dust–human	Tractor operator exposed to 10 mg/m^3 total dust while tilling a field to which sewage sludge has been applied.
12. Sludge–soil–surface water–contaminated water–fish toxicity–human toxicity.	Protection of human health and aquatic life. Risk to surface water associated with run-off of pollutants from soil on which sewage sludge has been applied. Water quality criteria are designed to protect human health assuming exposure through consumption of drinking water and resident fish and to protect aquatic life.
13. Sludge–soil–air–human	Protection of members of farm households inhaling vapors of any volatile pollutant that may be in the sewage sludge when it is applied to the land. This pathway is not applicable to inorganic pollutants. It is assumed that the total amount of pollutant spread in each year would be vaporized during that year.
14. Sludge–soil–groundwater–human	Exposure of individuals drinking water from groundwater directly below a field to which sewage sludge has been applied.

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$$\text{RIA} = \frac{0.0008 * 70}{1.0} 0.012 * 10^3 = 44\,\text{mg} \tag{11.2}$$

The RIA is used to determine the cumulative amount of a pollutant that can be land applied from biosolids for the selected pathway without adverse effects. In this case, Pathway 1 (an adult over a lifetime, consumes crops grown on biosolids-amended soil) is used as an illustration.

$$\text{RP}_c = \frac{\text{RIA}}{\hat{\text{A}}(\text{UC} \times \text{DC} \times \text{FC}} \tag{11.3}$$

where

RP_c = the cumulative amount of a pollutant that can be land applied, without adverse effects, from biosolids exposure through the pathway evaluated.
UC = plant uptake slope for pollutant from soil amended with biosolids.
DC = dietary consumption of different food groups grown in soils amended with biosolids.
FC = fraction of different food groups assumed to be grown in soils amended with biosolids.

The product of UC × DC × FC is 0.00654. Therefore, for arsenic in biosolids as applied to Pathway 1, the cumulative amount that can be land applied without adverse effects is 6700 kg/ha of As biosolids.

$$\text{RP}_c = \frac{44}{\hat{\text{A}}\text{UC} \times \text{DC} \times \text{FC}} = 6700\,\text{kg/ha} \tag{11.4}$$

The most limiting pathway for As was Pathway 3, a child ingesting biosolids. This analysis is shown below:

$$\text{RIA} = \frac{0.0008 * 16}{1.0} 0.0045 = 8.3\,\text{mg} \tag{11.5}$$

The principal difference in the calculation of equation (5) vs. equation (2) is the body weight (BW) of a child (16 kg) vs. that of an adult (70 kg). Also, the total intake of As for a child is 0.0045 mg/day vs. 0.012 mg/day for the adult.

The next step in calculating the concentration of a pollutant (RSC) in biosolids that can be expected not to produce adverse effects is as follows:

$$\text{RSC} = \frac{\text{RIA}}{\text{I}_s * \text{DE}} \tag{11.6}$$

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where

RSC = concentration of a pollutant in biosolids that can be ingested without the expectation of adverse effects
RIA = amount of pollutant ingested by humans without expectation of adverse effects
I_s = rate of biosolids ingestion by children
DE = exposure duration adjustment; an attempt to consider less than lifetime exposure

The RSC for As concentration in biosolids ingested by children is calculated as follows:

$$\text{RSC} = \frac{8.3}{0.2 * 1} = 41\,\text{mg} \tag{11.7}$$

Similar assessments were conducted for other potential As toxicity pathways.

Phytotoxicity of inorganic elements (Pathway 8) was evaluated in two different methods:

Method I

- A phytotoxicity threshold (PT_{50}) was established. This value is the concentration of a pollutant that can cause a 50% reduction in plant growth. This was based on short-term data.
- A calculation was made to determine the probability that the heavy metal concentration in plants grown on biosolids-amended soil would exceed the PT_{50} at various metal loadings using field studies.
- An acceptable level of tolerable risk exceeding the PT_{50} was set at 0.01 (i.e., 1 out of 100 times).
- The allowable loading rate of biosolids (RP) was the rate that would have less than 0.01 probability of causing the PT_{50} to be exceeded.

The example provided below is for zinc.

- The PT_{50} for Zn = 1975 μg Zn/g plant tissue dry weight.
- The probability that corn grown on biosolids-amended soils would exceed the PT_{50} was computed for 12 Zn loading ranges.
- The tolerable risk for exceeding PT_{50} was set at 0.01.
- None of the loading rates evaluated exceeded the probability of 0.01. Therefore the highest loading rate evaluated (3,500 kg Zn/ha) was chosen as the allowable loading rate (RP) for biosolids that would not cause a significant phytotoxic effect in corn. RP = 3500 kg Zn/ha.

Method II

$$\text{RP} = \frac{\text{TPCBC}}{\text{UC}} \tag{11.8}$$

This method evaluated the lowest-observed-adverse-effects-level (LOAEL). The reference cumulative application rate of a (RP) of Zn was calculated as follows.

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Where:

RP = The amount of a pollutant that can be applied to a hectare of land without expectation of adverse effects
TPC = The concentration of a pollutant in a sensitive plant tissue species (e.g., lettuce, as opposed to a less sensitive species, such as corn, used in method I)
BC = Background concentration of pollutant in plant tissue
UC = Plant uptake of pollutant from soil/biosolids

For Zn the following parameters were used:

TPC = 400 mg of Zn/g plant tissue in lettuce dry weight (mg/g DW)
BC = 47.0 mg of Zn/g plant tissue of lettuce DW
UC = 0.125 mg of Zn/g of lettuce plant tissue (kg of Zn per ha) (mg/g DW)(kg/ha)

The calculation of RP for Zn is as follows:

$$RP = \frac{40047.0}{0}.125 = 2800\ \text{kgZn / ha}$$

A comparison of the results of Method I (3500 kg Zn/ha) and II (2800 kg Zn/ha) shows that the more restrictive result was an RP of 2800 kg Zn/ha. The limit set for Pathway 8 was the pollutant limit used in the Part 503 rule for Zn.

Table 11.2 summarizes the pollutant limits for heavy metals in biosolids and biosolid products (USEPA, 1995). Prior to reviewing the pollutant limits, an explanation of the following definitions is in order:

- Ceiling concentration – This is the maximum concentration in mg/kg of an inorganic pollutant (heavy metal) in biosolids compost that is allowed for land application. If biosolids contain pollutants above these levels, the product may not be applied to land. Below this limit, other criteria may restrict its use. States may issue regulations that have lower limits, but not higher ones.
- Pollutant concentration (PC) limits – The pollutant concentration limit is the maximum concentration in mg/kg of an inorganic pollutant and applies to Class B biosolids.
- Cumulative Pollutant Loading Rate (CPLR) – This is the maximum amount of an inorganic pollutant that can be applied to an area of land.
- Alternative Pollutant Limit (APL) – This is the highest level of a given heavy metal in biosolids that is permitted in materials to be marketed.
- Exceptional Quality Biosolids (EQ) – Although this term is not used specifically in the 503 regulations, it is used in documents published by USEPA explaining the 503 regulations (USEPA, 1994). It refers to the concentration of a low pollutant in biosolids that meets the USEPA no observed adverse effects limits (NOAEL) criteria, as well as the pathogen and vector attraction reduction requirements.
- Annual Pollutant Loading Rate (APLR) – This is the highest annual (365 days) rate of application of each pollutant to land in kg/ha.

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Table 11.2 Pollutant Limits for Heavy Metals in Biosolids and Biosolids Products

Pollutant	Ceiling Concentration Limits for all Biosolids Applied to Land mg/kg[1]	Pollutant Concentration Limits for EQ and PC Biosolids mg/kg[1]	Cumulative Pollutant Loading Rate Limits for CPLR Biosolids kg/ha	Annual Pollutant Loading Rate Limits for APLR Biosolids kg/ha/365-Day Period
Arsenic	75	41	41	2.0
Cadmium	85	39	39	1.9
Copper	4,300	1,500	1,500	75
Lead	840	300	300	15
Mercury	57	17	17	0.85
Molybdenum[2]	75	–	–	–
Nickel	420	420	420	21
Selenium	100	36	100	5.0
Zinc	7,500	2,800	2,800	140
Applies to:	All biosolids that are land applied	Bulk biosolids and bagged biosolids[3]	Bulk biosolids	Bagged biosolids[3]
From Part 503	Table 1, Section 503.13	Table 3, Section 503.13	Table 2, Section 503.13	Table 4, Section 503.13

[1] Dry-weight basis.

[2] The limits for molybdenum were deleted from the 503 rule on February 25, 1994 (*Fed. Reg.*, Vol. 39, No. 38, p. 9095).

[3] Bagged biosolids sold or given away in bag or other container.

[4] Chromium deleted from regulations and selenium modified in 1995.

Source: USEPA, 1995.

In addition to pollutant limits, the 503 rule also required pathogen and vector attraction reduction criteria. The basis for the 503 pathogen requirements are provided in the USEPA document Technical Support Document for Reduction of Pathogens and Vector Attraction in Sewage Sludge (USEPA, 1992). In October 1999, USEPA issued a revision of the document Environmental Regulations and Technology Control of Pathogens and Vector Attraction in Sewage Sludge (EPA/625/R-92-013). In the previous USEPA 257 regulations, the only requirements for composting were based on time-temperature relationships.

In a 1988 study, Yanko demonstrated that regrowth of pathogens occurs in biosolids compost. In this study, salmonellae were detected 165 times in 365 measurements. No salmonellae were detected in the 86 measurements for which the fecal coliform densities were less than 1000 MPN (most probable number)/g. This indicated that the potential for finding salmonellae would be highly unlikely when the fecal coliform densities were less than 1000 MPN/g (USEPA, 1992; Farrell, 1992). USEPA (1992) states that the reason for alternately using the fecal coliform test or the salmonellae test is that fecal coliform can regrow to levels exceeding 1000 MPN/g, but once totally eliminated, salmonellae can never grow.

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USEPA required that sewage sludge be treated to reduce the potential for insects, birds, rodents and domestic animals to transport sewage sludge and pathogens to humans. These vectors are attraced to sewage sludge as a food source. The Part 503 regulations required that sewage sludge be treated to reduce vector attraction. Vector attraction reduction (VAR) could be achieved in two ways: 1) by treating the sewage sludge to the point at which vectors will no longer be attracted to it and 2) by placing a barrier between the sewage sludge and vectors.

Subpart D (503.33) provides for 12 options necessary to demonstrate VAR. Options 1 to 8 apply to sewage sludge that has been treated to reduce vector attraction. These options consist of either operating conditions or tests to demonstrate the vector attraction has been reduced in the treated sewage sludge. Options 9 through 11 are "barrier" options. These aply to both biosolids and domestic septage. Details are provided in the USEPA document Control of Pathogens and Vector Attraction in Sewage Sludge, EPA/625/R-92/013, 1999.

For Class A biosolids, pathogen reduction must take place before or at the same time as vector attraction reduction occurs. In the options 6, 7 and 8, this does not apply.

The 503 regulations also provide sampling and analysis methodologies. One of the most important aspects of the 503 regulations, which impact land application methodologies, is liability. Direct land application, whether by a public or private entity, is the legal responsibility of the producer of biosolids. If a municipality or its contractor violates the permit requirement for land application of biosolids, the producer, its employees and the contractor are subject to civil and criminal action. For example, if a contractor violates the municipality's permit to apply a specific quantity of biosolids containing the 503 heavy metal limitations, the contractor, the municipality and any knowledgeable individuals can be liable and sued for both criminal and civil damages.

The distribution and marketing of biosolids products, such as compost, does not entail similar liability. A contractor or individual purchasing compost containing the limit of heavy metals and distributing or marketing the compost at excessive rates does not face criminal or civil charges. Only product liability litigation could result (e.g., if compost is provided to a user without adequate instruction on its use and it causes phytotoxicity).

Pathogens in sewage sludge, biosolids and septage are regulated under Subpart D of the part 503 rule (USEPA, 1999). Two classes are designated: Class A and Class B. Class A is designed so that pathogens are not detected in biosolids or biosolids products. These include bulk or bagged products that are given away for home gardens or other horticultural uses. Once sewage sludge is treated to meet Class A or Class B, it can be designated as biosolids. This distinguishes it from untreated material.

The pathogen regulations involve three aspects:

1. Specific pathogen requirements
2. Process requirements
3. Vector attraction requirements (VAR)

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CLASS A REQUIREMENTS

Pathogen requirements are as follows:

- The density of fecal coliform in the sewage sludge or biosolids must be less than 1,000 most probable number (MPN)/g total solids (dry-weight basis).

or

- The density of *Salmonella* sp. bacteria in the sewage sludge or biosolids must be less than 3 MPN per 4 g of total solids (dry-weight basis).

Either of these requirements must be met at one of the following times:

- When sewage sludge or biosolids are used or disposed
- When sewage sludge or biosolids products such as compost, alkaline stabilized material, or heat-dried products are prepared for sale or giveaway in a bag or other container for land application; or
- When the sewage sludge or biosolids product or derived materials are prepared to meet the requirements for EQ biosolids.

Pathogen reduction must take place before or at the same time as VAR.

Process Requirements

Six alternatives exist for treating sewage sludge or biosolids so that they can meet Class A pathogen requirements. These are:

Alternative 1—Thermally Treated Sewage Sludge [(503.32(a)(3)]

Pathogen requirements as stated above must be met.

Biosolids must be subjected to one of four time-temperature regimes. Each regime is based on the percentage of solids of the sewage sludge and on operating parameters. Vector attraction (VAR) is met by reducing the volatile solids by more than 38%.

Alternative 2—Sewage Sludge Treated in a High pH–Temperature Process (Alkaline Treatment) [503.329(a)(94)].

The process conditions required are:

- Elevated pH to greater than 12 hours and maintaining the pH for more than 72 hours.
- Maintaining the temperature above 52°C (126°F) throughout the sewage sludge for at least 12 hours during the period that the pH is greater than 12.
- Air drying to over 50% solids after the 72-hour period of elevated pH.
- VAR option 6, pH adjustment; pH to remain elevated until use/disposal.

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Alternative 3—Sewage Sludge Treated in Other Processes [503.32(a)(5)]

This alternative relies on comprehensive monitoring of bacteria, enteric viruses and viable helminth ova to demonstrate adequate reduction of pathogens. VAR depends on the process by which pathogen reduction is met (one to 11 VAR options).

Alternative 4—Sewage Sludge Treated in Unknown Processes [503.31(a)(6)].

The requirements are similar to Alternative 3. Pathogen monitoring is required and testing is to be done at the time the sewage sludge is used or disposed. VAR is demonstrated by showing a 38% volatile solids reduction. VAR depends on the process by which pathogen reduction is met (one To 11 VAR options).

Alternative 5—Use of Process to Further Reduce Pathogens (PFRP) [503.32(a)(7)]

Sewage sludge is considered Class A if is treated by PFRP as listed and the Class A pathogen requirements are met. VAR must be met. PFRP processes include:

- Composting
- Heat drying
- Heat treatment
- Beta ray irradiation
- Gamma ray irradiation
- Pasteurization

Alternative 6—Use of a Process Equivalent to PFRP [503.32(a)(8)]

The requirements are similar to Alternative 5.

CLASS B REQUIREMENTS

Class B requirements can be met in three different ways.

- Monitoring of indicator organisms — tests for fecal coliform density as an indicator organism for all pathogens. The geometric mean of seven samples shall be less than two million MPNs per gram total solids or less than two million CFUs (colony-forming unit) per gram of total solids at the time of use or disposal.
- Sewage sludge is treated in processes to significantly reduce pathogens (PSRP).
- Sewage sludge treated in a process equivalent to a PSRP.

In addition to these requirements, site restrictions for Class B sewage sludge are applied to land.

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Table 11.3 Maximum Acceptable Heavy Metal Concentrations and Maximum Acceptable Cumulative Heavy Metal Additions to Soil

Heavy Metal	Maximum Acceptable Metal Concentrations mg/kg[1]	Maximum Acceptable Cumulative Heavy Metal Additions to Soil kg/ha
As	75	15
Cd	20	4
Cu	150	30
Pb	500	100
Hg	5	1
Mo	20	4
Ni	180	36
Se	14	2.8
Zn	1,850	370

[1] In processed sewage, sewage-based products and other by-products containing 5% N or less and represented for sale as fertilizer.
Source: Agriculture and AgriFood Canada, Trade Memorandum, T-4-93, July 1995.

CANADA

Canadian provinces set regulations or guidelines for biosolids' heavy metal concentrations and limits to be applied to soils. Table 11.3 shows the maximum acceptable heavy metal concentrations and maximum acceptable heavy metal additions to soil as recommended by the Ministry of Agriculture. Canadian provinces can set their own limits, which are shown in Table 11.4.

Table 11.4 Canadian Provincial Guidelines for Heavy Metals

Heavy Metal	Nova Scotia	Ontario	Alberta Class A	British Columbia
		Concentration - mg/kg dw		
Cd	2.6	3	<2	2.6
Cu	100	60	<80	100
Cr	210	50	<100	210
Pb	150	150	<50	150
Hg	0.83	0.15	<0.2	0.83
Ni	50	60	<32	50
Zn	315	500	<120	315

Source: Dillon, 1994.

A recent document prepared for the Water Environment Federation of Ontario (WEAO, 2001) reviewed the literature on fate and significance of selected contaminants in sewage biosolids applied to agricultural land. The Ontario guidelines, introduced in the mid-1970s, recommended applying liquid anaerobically stabilized biosolids at a rate not to exceed 135 kg of plant available N per hectare per 5 years. This is based on the amount of N needed to grow corn. The heavy metal guidelines,

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Table 11.5 Ontario Guidelines for Heavy Metals in Biosolids and Agricultural Soils

Heavy Metal	Anaerobic Biosolids Minimum (Ammonium + Nitrate) Nitrogen to Metal Ratios	Aerobic, Dewatered and Dried Biosolidsmg/kg Dry Weight	Maximum Permissible Metal Concentrations in Soil mg/kg Dry Weight	Maximum Permissible Metal Loading to Soil mg/kg Dry Weight
Arsenic	100	170	14	14
Cadmium	500	34	1.6	1.6
Cobalt	50	340	20	30
Chromium	6	2800	120	210
Copper	10	1700	100	150
Lead	15	1100	60	90
Mercury	1500	11	0.5	0.8
Molybdenum	180	94	4	4
Nickel	40	420	32	32
Selenium	500	34	1.6	2.4
Zinc	4	4200	220	330

Based on Guidelines for the Utilization of Biosolids and Other Wastes on Agricultural Land. Ontario Ministry of the Environment and Energy and Ontario Ministry of Agriculture, Food and Rural Affairs, Toronto, ON.
Source: WEAO, 2001. With permission.

based on background levels for soils, are shown in Table 11.5. This concept is flawed because use of pesticides, herbicides and fertilizers containing heavy metals is allowed, even though they exceed background levels.

EUROPE

Regulations vary among European countries. These regulations are essentially based on the no-net-degradation approach that has strict limitations. As McGrath et al. (1994) point out, the scientific basis for many of the limits in European countries is difficult to find. Furthermore, in those countries that have a short history of biosolids disposal, the scientific basis is totally lacking. The European Union (EU) has its own standards. The EU is a federation of 15 sovereign states in Western Europe. While the EU encourages the use of biosolids, the EU directive 86/278/EEC regulates its use to prevent harm to the environment — especially soils (Langenkamp and Part, 2001). Table 11.6 shows the current and projected heavy metal limits proposed by the EU (Matthews, 1999; EC, 2000).

Differences in several European countries are illustrated in Table 11.7. The heterogeneity in ecological and economic conditions makes it very difficult to establish consensus in Europe. In some cases, ecology or the need to preserve the limited agricultural soils in a country is the driving force. Many soils in central Europe are contaminated due to long-term industrial pollution. In other countries, economics is the driving force. Farmers need biosolids as a nutrient source and to reduce their fertilizer costs. It appears that the EU standards set an overall condition

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Table 11.6 Limit Values for Concentrations of Heavy Metals in Biosolids and Limits to Annual Additions of Metals to Soil Based on a 10-Year Average

Element	Current		Proposed 2015		Proposed 2025	
	Limit Values for Concentrations mg/kg dm	Limit Values for Annual Additions g/ha/y	Limit Values for Concentrations mg/kg dm	Limit Values for Annual Additions g/ha/y	Limit Values for Concentrations mg/kg dm	Limit Values for Annual Additions g/ha/y
Cd	20–40	150	5	15	2	6
Cr	–	–	800	2400	600	1800
Cu	1000–1750	12000	800	2400	600	1800
Hg	16–25	100	5	15	2	6
Ni	300–400	3000	200	600	100	300
Pb	750–1200	1500	1500	1500	200	600
Zn	2500–4000	30000	2000	6000	1500	4500

Source: McGrath et al., 1994.

Table 11.7 Comparison of Concentration Limits for Heavy Metals in Biosolids Used for Land Application between the United States and Several European Countries

Element	U.S.[1]	EU	Netherlands	Sweden	Denmark	Germany
			mg/kg/Dry Weight			
As	41	—	0.15	—	25	—
Cd	39	20–40	1.25	2	0.8	5–10
Cr	(1200)[2]	—	75	100	100	900
Cu	1500	1000–1750	75	600	1000	800
Hg	17	16–25	0.75	2.5	0.8	8
Pb	300	750–1200	100	100	60–120	900
Ni	420	300–400	30	50	30	200
Zn	2800	2500–4000	300	800	4000	2000–2500

[1] USEPA regulations 40 CFR 503.
[2] Cr subsequently deleted from regulations.

for the countries, yet individual countries, such as Sweden, can have more restrictive standards.

Table 11.7 shows that considerable variation exists within the EU. This variation likely reflects the lack of scientific basis. It appears that, in many cases, values were arbitrarily selected and not based on risk assessment. Harrison et al. (1999) indicate that countries such as Sweden, Denmark and the Netherlands use a philosophy of "do no harm" to protect soil quality. This concept is based on the "no net degradation" concept (i.e., that inputs do not exceed outputs).

Loading limits are shown in Table 11.8.

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Table 11.8 A Comparison of Loading Limits in kg/ha/Year in the United States and European Union[1]

				Proposed future EU limits		
Element	USEPA	EU[2]	Lowest member state	Current to 2015	2015–25	After 2025
As	2	–	0.25 Denmark[3]	–	–	–
Cd	1.9	0.15	0.002 Sweden	0.03	0.015	0.006
Cr	150	–	0.1 Sweden	3.0	2.4	1.8
Cu	75	12	0.6 Sweden	3.0	2.4	4.8
Hg	0.85	0.1	0.001 Finland	0.03	0.015	0.006
Pb	15	15	0.1 Sweden	2.25	1.5	0.6
Ni	21	3	0.05 Sweden	0.9	0.6	0.3
Se	5	–	0.15 UK[4]	–	–	–
Zn	140	30	0.8 Sweden	7.5	6.0	4.5

[1] Excluding the Netherlands.
[2] The loading rate is averaged over 10 years.
[3] Only the U.K. and Denmark regulate As.
[4] Only the U.K. regulates Se.

Source: Evens, 2001.

Several countries also have standards for concentrations of organic contaminants in biosolids. EU standards are as follows: Halogenated organic compounds 500 mg/kg dm; DEHP, 100 mg/kg dm; LAS, 2600 mg/kg dm; NP/NPE 50 mg/kg dm; PAH, 6 mg/kg dm; PCB, 0.8 mg/kg dm; and PCDD/F, 100 mg TEQ/kg dm. Denmark has standards for DEHP, LAS, NP/NPE and PAH; Sweden for NP/NPE, PAH and PCB; and Germany for PCB and PCDD/F. In these countries, the standards are equal to or lower than the EU standards.

CONCLUSION

The USEPA regulations are risk based. The agency is in the process of reviewing and supplementing the regulations. The next round of regulations will address selective organic compounds.

Although the scientific community in the United States in general has supported the USEPA regulations, a vocal minority believes that the 503 rule is not sufficiently protective of human health and the environment. Their concerns merit a brief discussion.

Several points need to be made or reemphasized. The 503 rule was risk based. This rule is constantly subject to changes as new research data become available. No other waste or product has been subjected to such extensive research and examination. In 1996, the National Research Council of the National Academy of Sciences issued a report entitled, "Uses of Reclaimed Water and Sludge in Food Crop Production." A second review by the National Research Council was published in draft form on July 2, 2002.

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Here are some of the major findings and recommendations:

1. The committee recognized that land application of biosolids is a widely used, practical option for managing the large volume of sewage sludge generated in the United States that otherwise would be incinerated or landfilled.
2. The committee did not find documented scientific evidence that the Part 503 regulations had failed to protect public health. Additional scientific work is needed to reduce uncertainties about the potential adverse public effects from exposure to biosolids.
3. There is a need to update the scientific basis of the rule as related to chemical and pathogen standards, demonstrate that there is effective enforcment of the Part 503 rule and validate the effectiveness of biosolids management practices.
   - There is a lack of exposure and health information on poulations exposed to biosolids.
   - There has been no substantial reassessment to determine whether the chemical and pathogen standards promulgated under the Part 503 Rule in 1993 are supported by current scientific data and risk assessment.
   - The technical basis of the 1993 chemical standards for biosolids is outdated.
4. The committee supports USEPA's approach to establishing pathogen reduction requirements and monitoring indicator organisms. Better documentation is needed using current pathogen detection methods; there is a need for better research on environmental persistence and for determining dose–response relationships to verify that the current management controls for pathogens are adequate to maintain minimal concentrations of pathogens over extended periods of time.
5. The major recommendations are:
   - Use improved risk-assessment methods to establish standards for chemicals and pathogens.
   - Conduct a national survey of chemicals and pathogens in sewage sludge.
   - Establish a procedural framework for implementing human health investigations.
   - Increase the resources for USEPA's biosolids program.

For more information, a prepublication of the report, entitled Biosolids Applied to Land: Advancing Standards and Practices, is available from the Committee on Toxicants and Pathogens in Biosolids Applied to Land, Board on Environmental Studies and Toxicology, Division of Earth and Life Sciences, National Research Council, Washington, D.C.

Several scientists at Cornell University and at the Cornell University Waste Management Institute, Center for the Environment, indicated that the current U.S. federal regulations governing land application of biosolids do not appear to adequately protect human health and the environment (Harrison et al., 1999). They point out that the U.S. regulations are much less protective than the Canadian or European guidelines or regulations. Their main arguments follow:

- Pollution is allowed to reach maximum "acceptable" level. Without a very good understanding of pathways and processes, it is unwise to allow pollutants to reach calculated maximum acceptable values.
- Each exposure pathway was evaluated separately and did not account for multiple pathways of exposure or synergy. Often risk assessments use an additive approach.
- USEPA calculated cancer risk of 1 in 10,000 vs. 1 in 1,000,000. This resulted in less restrictive values.

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- The soil ingestion rate by children of 200 mg/day may be too low and the period of five years too short.
- The pollutant intake through food was underestimated. The USDA recommended intake of vegetables and fruits is much higher than the intake estimates used by USEPA.
- The plant uptake coefficients were very low. These coefficients express the amount an element is taken up by the plant as compared with the amount in the soil.
- Many pollutants are not regulated or monitored. These include pollutants where insufficient data exist, such as synthetic organic chemicals and radioactivity in sludges. USEPA is currently evaluating organic chemicals and radioactivity in sludges.
- Ground and surface water calculations assume large dilution/attenuation.
- Insufficient attention was given to phytotoxic effects and effects on soil microorganisms and animals.

Regulations on biosolids management are important. The risk-based approach used by USEPA provides opportunity to modify regulations as better scientific data become available. The enforcment of the regulations is problematic. USEPA does not have the means to oversee the regulations. Even if states receive authorization to enforce regulations, they often lack the funds and personnel. Public confidence will be enhanced if the public perceives that the regulations are adequate to protect human health and the environment and that the regulations are enforced.

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